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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,894	01/30/2004	Kobi Iki	00167-491001/02-31-0464	4190
<div>7590 Joel R. Petrow, Esq. Chief Patent Counsel Smith & Nephew, Inc. 1450 Brooks Road Memphis, TN 38116</div>				
11/17/2008				
EXAMINER				
PEFFLEY, MICHAEL F				
ART UNIT		PAPER NUMBER		
3739				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/766,894

Applicant(s)

IKI ET AL.

Examiner

Michael Peffley

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 20-46 is/are pending in the application.
- 4a) Of the above claim(s) 3, 5-7, 9, 10, 13-16, 25-30, 36, 39 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 8, 11, 12, 17, 20-24, 31-35, 37, 38, 40, 41 and 43-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 November 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Applicant's arguments, filed August 7, 2007, have been fully considered by the examiner now of record. After further consideration of the claims and the prior art, the examiner now issues the following Office action which is a non-final action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8, 11, 12, 17, 20-23, 31, 33-35, 37, 38, 40, 41 and 43-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Haissaguerre et al (6,068,629).

Haissaguerre et al disclose an electrosurgical instrument comprising a shaft (28) having a flexible portion (142,144,154 - Figure 13) and a head (152) coupled to the shaft through the flexible portion. The head is pivotally coupled to the flexible portion (154) as shown in Figure 13C,"and the head includes a planar, non-conductive surface (152) having a plurality of conductive surfaces (160) mounted thereon. The electrodes may be recessed in the head as shown in Figures 6 and 13, or the electrodes may protrude from the head as shown in Figures 9 and 10. The examiner maintains that once deployed, the flexible portion is configured to passively bias the conductive surface towards tissue. The head contains a slot (Figure 13c) about which the head is configured to pivot. The method of using the device to treat tissue is inherent to the structure and is fully disclosed by Haissaguerre et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haissaguerre et al ('629).

Haissaguerre et al disclose applicant's invention as addressed previously, but fail to specifically disclose the use of a nitinol or spring wire in the flexible portion. It is noted that Haissaguerre et al clearly disclose a flexible wire member, and also teach of the use of nitinol (col. 8, line 65). The examiner maintains that the use of any well known flexible material, such as nitinol or spring steel, for making the flexible actuator members would have been an obvious design consideration for one of ordinary skill in the art, particularly considering that Haissaguerre et al disclose the use of such materials.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haissaguerre et al ('629) in view of the teaching of Hall et al (6,290,699).

Haissaguerre et al fail to disclose the particular "T-shaped" electrode recited in this claim.

Hall et al disclose another electrosurgical device that includes a head member (140) supported on an elongate member (120), the head member having a plurality of

electrodes (130) mounted on a non-conductive portion of the head member. In particular, Hall et al teach that the electrodes on the head member may be provided with a variety of shapes, as shown in Figures 2-9. The examiner maintains that to have provided any desired electrode pattern would be an obvious design choice. It is further noted that applicant's specification is void of any criticality or unexpected result associated with the particular shape for the electrode structure.

To have provided the Haissaguerre et al device with electrodes formed on the head member in any desired shape, including a "T-shape", to treat a particular region of interest is deemed an obvious design modification for one of ordinary skill in the art, particularly since Hall et al teach that it is known to provide various electrode shapes as a matter of design choice on an analogous device.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haissaguerre et al ('629) in view of the teaching of Parins et al (5,125,928).

Haissaguerre et al disclose an elongate member, but fail to specifically disclose a sheath provided for covering the flexible portion of the head for delivery of the ablation head to tissue.

Parins et al disclose another RF device that includes a shaft (62) and a pivotally mounted head (80) mounted to the shaft. Electrodes are provided on the head member for treating tissue. Further, Parins et al teach that it is known to provide a sheath member (60) which covers the flexible portion of the shaft and the head member prior to deployment to assist in delivering the device to a tissue site.

To have provided the Haissaguerre et al device with a sheath member to cover the head during insertion of the device to a treatment site would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Parins et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 17 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/999230. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims specify: a shaft, a flexible portion, and a head coupled to the shaft through the flexible portion and pivotably coupled to the flexible portion, the head including a non-conductive surface and an electrically

conductive surface, wherein the flexible portion is configured to bias the non-conductive surface and the electrically conductive surface towards a tissue surface.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 17 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 3 of copending Application No. 10/999230. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims specify: a shaft, a flexible portion, and a head coupled to the shaft through the flexible portion and pivotably coupled to the flexible portion, the head including a non-conductive surface and an electrically conductive surface, wherein the flexible portion is configured to bias the non-conductive surface and the electrically conductive surface towards a tissue surface. Furthermore, it would be obvious, if not inherent, for the non-conductive surface of 10/999230 to be adjacent at least a portion of the electrically conductive portion, since the non-conductive portion limits penetration of the electrically conductive surface into the tissue surface.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 43 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 12 of copending Application No. 10/999230. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims specify: a shaft, a resiliently flexible portion, and a head coupled to the shaft through the resiliently flexible portion, the head being pivotably coupled to the resiliently flexible portion, the head including a substantially planar tissue contact surface including a non-conductive portion and an electrically conductive portion.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-2, 4, 8, 11-12, 17, 20-24, 31-35, 37-38, 40-41, and 43-46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 12 of copending Application No. 10/999230. Although the conflicting claims are not identical, they are not patentably distinct from each other because the more specific claims of 10/999230 encompass the broader claims in 10/766894. In addition, the "resiliently flexible portion" and "to passively bias" of 10/999230 are elements that are obvious and well-known to one of ordinary skill in the art. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

It is noted that the Haissaguerre et al reference was used in a rejection by the previous examiner in the Office action of August 18, 2006. Applicant had amended the claims in the response of November 16, 2006 and added the language that the flexible portion is "configured to passively bias the electrically conductive surface towards tissue". Applicant argued that the Haissaguerre et al flexible portion is manually steered using a manipulator wire and is therefore not "passively biased". While the examiner agrees that steering wires are used in Haissaguerre et al to deploy the head member (and the electrodes), this does not preclude the flexible portion from being "configured to passively bias" the electrode surface towards tissue. The examiner maintains that once the Haissaguerre head is fully deployed, the steering wires become passive elements with an inherent amount of resiliency. The natural resiliency of the wire members would inherently bias the head members towards tissue and would resiliently resist pressure applied towards the head members in the proximal direction. As such, the examiner now of record maintains the Haissaguerre et al device continues to anticipate and obviate the claims as set forth in the previous rejections.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ingle et al (6,572,639) disclose another device comprising an elongate member having a flexible distal end with a non-conductive head member including a plurality of electrodes mounted to the head (Figure 5b).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner, Art Unit 3739

/mp/
November 12, 2008

